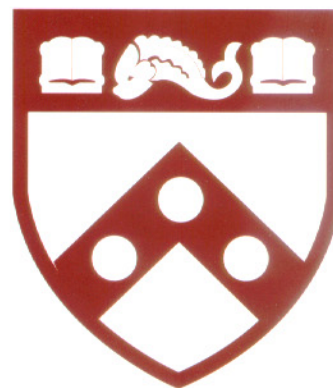




*Consent to Participate*

# UNIVERSITY OF Pennsylvania Cancer Genetics NETWORK

*You are being invited to join a  
research program called the  
University of Pennsylvania Cancer  
Genetics Network. This program  
is part of the Cancer Genetics  
Network, sponsored by the  
National Cancer Institute, which  
is enrolling participants through  
out the United States.*



*Principal Investigator*  
**Barbara Weber, M.D.**

University of Pennsylvania  
**CANCER CENTER**  
University of Pennsylvania Health System



## **What is the National Cancer Genetics Network?**

The National Cancer Genetics Network is a national effort to develop a resource to help researchers better understand what causes cancer and how to improve its detection, prevention, and treatment. For this project, researchers are most interested in studying families in which there is a history of cancer. Many research studies need more participants than any one cancer research center can enroll. Therefore, the national network is made up of eight major sites, each selected by the National Cancer Institute for the excellence of their work in cancer genetics. Each site will invite people who may be willing to be in future cancer research studies in the network.

## **Why is there a need for a National Cancer Genetics Network?**

By combining people from all of the network sites, this national network will provide a way for researchers to increase the number of study participants for certain research projects. This will make it possible for the research to happen more quickly and effectively. The national Network will also contribute to cancer research by gathering some basic medical and family history information about each participant. This information will be updated every year and will be useful in answering some basic research questions about cancer and genetics.

## **Who is being invited into the University of Pennsylvania Cancer Genetics Network?**

*You will be invited to be in the local network if:*

- You have had breast, ovarian, colon, melanoma, rectal, or prostate cancer; or
- You have one of several rare forms of cancer known to be hereditary; or
- You are closely related to someone who has had one of these cancers.

At the University of Pennsylvania Cancer Center, we hope to enroll at least 1,000 individuals into the local network.



## **Who is being enrolled in the National Cancer Genetics Network?**

Once you have been enrolled in the local network, we will determine whether to send your information to the national network based upon such factors as a family history of cancer. NO identifying information will be sent to the national network and no one from any other institution will be able to contact you unless you give us your permission. It is possible that the information you may provide may be used by the local network, but may not be sent to the national network.



## What else do I need to know?

### Voluntary Participation

Your participation in the local network is voluntary. You can choose not to participate in the network. If you sign this form, you agree to give the local network permission to use the information you provide and share it with the national network without identifying information. The national network may keep this information indefinitely and may use it in future research studies for an unlimited period of time.

You are free to withdraw from the local network at any time. If you choose to withdraw, you will still receive the same clinical care you would have otherwise received. If you withdraw, your information will be removed from both the local and national networks. Also, participation in the local network may be stopped by the investigator without your consent.

### Financial Costs

You will receive no money for enrolling in the network, nor will you have to pay to be in the network. If you decide to participate in a future research study, there may be costs associated with that study which would be explained to you at that time.

### Medical Treatment or Compensation for Injury

In the event you sustain injury for your participation in a research project, medical treatment in excess of that covered by third party payers will be provided without cost to you, but additional financial compensation is not available.

### New Information

Sometimes the information that you have given us leads to new discoveries. If we learn something that can help people in our local network, we will share it with you.

### Contact Persons

If at any time you have questions or comments about the local network or your rights as a participant, you should contact Jill Stopfer, MS at **215-349-8143** or Kathleen Calzone, RN, MSN at **215-349-8141**.

### Institutional Review Board

The University of Pennsylvania has a committee called the Institutional Review Board. It is their job to make sure that people are informed about the risks and benefits of a particular research project. If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with us, please contact the Executive Director in the Office of Research Administration at the University of Pennsylvania by telephoning **215-898-7293**.







## What will I be asked to do if I join this network?

### 1 Complete a questionnaire

You will be asked to complete a short questionnaire. The questionnaire asks for information about you (such as age, sex, and ethnic background), your medical history, your health habits, and the history of any cancer in your family. In addition, some people who join the local network might be asked to ask their relatives for permission to be contacted by local network researchers. No information about you will be shared with your relatives without your consent. Again, this contact information will not be provided to the national network.

### 2 Allow us to contact you for updates

*Each year, the local network will contact you for two reasons:*

- To update your information and
- To make sure that you are still willing to participate

### 3 Consent to contact you about future research studies

Information you give to local network will be kept in a secure database. Researchers directly involved with the University of Pennsylvania Cancer Genetics Network will be able to use the information for approved research purposes. However, this information will be used only after your name has been removed.

Other researchers may need more information, a blood sample, or a sample of tissue from surgery you or one of your relatives have had. For example, a researcher at another cancer center may want to ask you for more information by telephone or by letter. Before we give the researcher your name, we will call or write to you and give you more information about that study. You can then let us know if you want to be in that study. If you agree to be in the study, we will ask your permission to give your name to the researcher.

If you are interested in participating in a future study, you will be asked to sign a separate consent form at that time. That means there will be two chances to decide about participating - first when you are asked to give your name to the researcher and then after the researcher has explained the complete study to you.

It is also possible that you might not be contacted about participating in a future study because you are not eligible for any of the proposed studies.

## What benefits will I receive by being in the network?

There may be no direct medical benefits that will result from your participation in the network. However, one benefit of being in the network is that we will provide you with information on a regular basis about the latest advances in cancer genetics as they occur, and provide you with an opportunity to participate in any prevention programs for which you might be eligible.





## What are the risks of participating?

People sometimes feel upset when asked questions about their personal or family history of cancer, like those in the basic information questionnaire. It is possible that you might find it disturbing when you are contacted in the future to update information or to determine your interest in participating in a research study.

Although we have made every effort to protect your confidentiality, there is a very small risk of loss of confidentiality associated with being a part of a network.

## How is my confidentiality protected?

Every effort will be made to protect your confidentiality. The following measures will be taken to secure the information you provide:

All personal information given to your local network, the University of Pennsylvania, will be kept in locked cabinets and secured computers. Your basic information, including information that can specifically identify you (such as your name, address, or date of birth) will be entered into a secure computer database at the University of Pennsylvania Cancer Center.

Information that can identify you will be separated from your other information, which will be given a code number. Information, such as age, sex, and medical history, may then be sent to the Cancer Genetic Network's national databank at the University of California at Irvine. Information from all participating national network centers will be stored in a national database by *code number only*.

Your information and the code number that links information to you will be kept at the University of Pennsylvania Cancer Center and will be available to *only* the staff here. In other words, no one outside of the University of Pennsylvania Cancer Center will ever be able to link your name with your information. Because your name and contact information will be on file only at the University of Pennsylvania Cancer Center, our staff will make all future contacts with you, unless you give your permission for someone else to contact you.

This research is covered by a Certificate of Confidentiality issued by the National Cancer Institute on behalf of the Secretary of the Department of Health and Human Services. The Certificate protects against involuntary release of information about you collected during the course of the study, although such information can be released if you or your guardian requests it in writing. The researchers involved in this project cannot be forced to disclose your identity or any information about you collected in this study in any legal proceedings at the Federal, State or local level, regardless of whether they are criminal, investigative, or legislative proceedings. However, the Certificate does not prevent the review of your research records under some circumstances (for example, under the Federal Food and Drug and Cosmetic Act or during the course of an internal program audit or evaluation).



*For questions or comments, please contact*  
**Jill Stopfer, MS** at 215-349-8143  
*or*  
**Kathleen Calzone, RN, MSN** at 215-349-8141

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**University of Pennsylvania Cancer Center**  
*of the*  
**University of Pennsylvania**

